12-2023

Toward Opt-In Consent for Pregnancy Testing

Kim D. Ricardo
UIC School of Law, kricardo@uic.edu

December, 2023

Toward Opt-In Consent for Pregnancy Testing

Kim D. Ricardo
Stephanie Tillman
B.A. Goodrum
Angel Shae Street
Ashish Prekumar, et al.

Journal of Midwifery & Women's Health www.jmwh.org

Commentary

Continuing Education

Toward Opt-In Consent for Pregnancy Testing

Stephanie Tillman[1,9], CNM, MSN, B. A. Goodrum[2,3], CNM, FNP, Angel Shae Street[4], CNM, WHNP-BC, Ashish Premkumar[5], MD, PhD, Kim D. Ricardo[6], JD, Jonah Fleisher[7,8], MD, MPH

INTRODUCTION

In many health care settings, patients provide a urine sample without knowing its intended use and before seeing the provider, only becoming aware a pregnancy test was performed when confronting a positive result. Although this common opt-out, noninformed approach may optimize clinic flow, there are countervailing patient concerns at stake: consent, possible diagnosis of pregnancy, documentation in the health record, ensuing care, and safety needs. This approach is not patient-centered and is potentially harmful, denying patients' bodily autonomy and possibly compromising their right to privacy. The *Dobbs v. Jackson Women's Health Organization* ruling serves as a catalyst for reconsidering pregnancy testing consent processes and documentation within a legal climate that criminalizes abortion decisions and care.[1] This article details ethical and legal implications of opt-out pregnancy test practices. We argue for opt-in consent to pregnancy testing consistent with a reproductive justice framework that is patient-centered, respects autonomy and privacy, reduces harm, and should be viewed as best practice, while acknowledging complexities if the patient declines pregnancy testing relevant to their care.

Consent in Health Care Ethics

Consent is an ongoing process through which a patient agrees to or decides against provider-recommended care, an ethical fulfillment of which upholds both bodily and decisional autonomy. Everyday consent practices can be categorized into *opt-in* and *opt-out* models of consent.[2] Opt-in consent models involve an explicit conversation with the patient about their desire to agree to a test, intervention, or recommendation. Conversely, opt-out consent models assume patient consent unless otherwise indicated. Both opt-in and opt-out consent models can offer clinical and ethical advantages, depending on the circumstances.[2] When operationalizing pregnancy testing that carries significant health, social, financial, or legal implications for the patient, pausing to consider which consent model best respects patient autonomy and decision-making is an important ethical endeavor.

Opt-out consent models delegate all responsibility to the patient to communicate their choice to decline care. This model can be an efficient way to streamline consultation and optimize time for care. However, this approach predetermines a best choice while broadly assuming each individual patient has awareness of their care, the right to decline all care, capacity to express concerns or decisions, and safety or power to do so. A common example of opt-out consent is a provider ordering a panel of tests without notifying the patient of nor receiving consent for each individual test.

Opt-in consent models delegate responsibilities first to the provider to explicitly review risks, benefits, and alternatives to a recommendation, and next to the patient to provide consent to or decide against recommended care. Informed consent and shared decision-making, as examples of the opt-in model, optimize an ethical approach to consent.[3] Explicit opt-in consent processes invite patient self-determination at each stage of the visit. Opt-in consent offers the opportunity to individualize care, uplift the values, concerns, and circumstances of each unique patient, and actively empower patients and providers to engage ethical principles of respect for autonomy and justice.

Current Pregnancy Testing Model

Clinic and hospital urine pregnancy testing most often takes the form of opt-out consent. Urine pregnancy testing (UPT) is performed to screen for pregnancy and avoid inadvertent harm to the pregnancy-capable person, an embryo, or fetus. UPT is commonly performed just before surgery, medical imaging, and in the emergency department before prescribing analgesics and other medicines that could harm a developing embryo. Pregnancy testing is also performed in the office before provision of contraception or before procedures like colposcopy and endometrial biopsy. Some providers may collect a urine sample for UPT before a visit as part of routine practice.

[1]Albert Gnaegi Center for Health Care Ethics, Saint Louis University, Saint Louis, Missouri
[2]Montefiore Medical Center, New York City, New York
[3]The Door, New York City, New York
[4]Independent Scholar, Cambridge, Massachusetts
[5]Obstetrics and Gynecology, College of Medicine, University of Chicago, Chicago, Illinois
[6]School of Law, University of Illinois at Chicago, Chicago, Illinois
[7]Clinical Obstetrics & Gynecology, University of Illinois at Chicago, Chicago, Illinois
[8]Section of Family Planning, Division of Academic Specialists of Obstetrics and Gynecology, Center for Reproductive Health, University of Illinois at Chicago, Chicago, Illinois
[9]Feminist Midwife, LLC, Chicago, Illinois

Correspondence
Stephanie Tillman
Email: sntillman@gmail.com

ORCID
Stephanie Tillman https://orcid.org/0000-0003-1030-6022

Continuing education (CE) is available for this article. To obtain CE online, please visit http://www.jmwhce.org. A CE form that includes the test questions is available in the print edition of this issue.

1526-9523/09/$36.00 doi:10.1111/jmwh.13597

Table 1. Recommendations for Opt-In Pregnancy Testing That Maintain Efficiency and Safety

Clinical Scenario	Recommendations
All scenarios	Use the CDC's history-based tool, "How To Be Reasonably Certain that a Woman Is Not Pregnant," which is considered more accurate than urine pregnancy testing (negative predictive value of 99%-100%).[19,20]
	UPT false negatives: if the health care provider cannot be reasonably certain that the patient is not pregnant based on these criteria, then a negative pregnancy test may be a false negative and would not help rule out pregnancy anyway.
	UPT false positives: UPTs can remain positive for weeks after the end of every pregnancy, including childbirth, miscarriage, abortion, and ectopic pregnancies. The test's clinical value in these scenarios is more difficult to determine.
	Redesign processes to perform opt-in pregnancy testing whenever possible. Consider carefully the clinical environment, including the legal risk to your patient population.
	For patients declining UPT, develop a standard waiver the patient may sign to permit tests and treatments that might cause harm if pregnant.
Emergency department triage	Obtain informed consent for pregnancy testing in triage, and document this discussion appropriately.
	Best practices include both verbal and written information in the patient's preferred language.
	Do not obtain pregnancy testing if patient may have been recently pregnant (result may be a false positive).
Office and surgical centers	Request urine samples only when necessary for testing, after discussion with patient.
	If requesting urine samples during the intake process, hold for testing if/when patient provides informed consent with clinician.
Radiology suites	Universal informed consent for UPT at registration, with clinicians available to discuss risks/benefits.
	Use evidence-based precautions such as pelvic shielding during x-rays and computed tomography scans, irrespective of pregnancy status.

Abbreviations: CDC, Centers for Disease Control and Prevention; UPT, urine pregnancy test.

UPT is a valuable tool because it is rapid, noninvasive, inexpensive, and highly accurate. Many providers protocolize opt-out pregnancy testing in these clinical situations to improve efficiency and safety because of the value of this information for patients and providers, reducing the chance of failing to diagnose a pregnancy. Logistical pressures often lead to requesting a urine specimen before the patient sees a clinician, and without clear discussion or consent about how the urine will be used or tested. Some patients may want to know that they are pregnant, whereas other patients may *not* want that information, may not want that information disclosed in their medical record, may be unsure of their provider's support for a potential abortion decision, or may be unsure of their legal rights to care.

Legal Implications Post-*Dobbs*

Under *Roe v. Wade*, the decision to seek an abortion was a constitutional right acknowledged nationwide and protected against undue state interference.[4] These reproductive freedoms held until June 2022 when the Supreme Court overturned *Roe* and returned the power to regulate and even ban access to reproductive health care services to the individual states.[1] This decision set into motion complicated interstate legal conflicts.[5] As of August 9, 2023, fifteen states currently have laws that outlaw abortion, some of which target health care providers by criminalizing abortions or attempted abortions as felonies.[6] A growing number of jurisdictions have passed laws attempting to shield patients and providers from potential criminal and civil liability stemming from out-of-state abortion bans.[7] Yet, the federal constitution instructs all states to comply with extradition requests for any person fleeing criminal prosecution.[8] The post-*Dobbs* legal landscape raises important concerns for health care providers in abortion-supportive states and the patients who seek their services. Even when patients are not directly targeted with liability, providers are.[9] The confusing patchwork of state laws threaten to have a chilling effect on litigation-averse providers and institutions.

Post-*Dobbs* abortion restrictions also raise questions about patient privacy and mandatory disclosures. The Department of Health and Human Services released guidance relating to disclosures of protected health information related to reproductive health care, affirming that the Health Insurance Portability and Accountability Act's privacy rule "permits but does not require" disclosure to law enforcement officials.[10] However, local and state mandatory reporting laws operate as exceptions in which mandatory reporting duties can be triggered by mere suspicion of criminal activity.[3,11] For fear of criminal and civil liability or other collateral consequences, patients may have good reasons for not wanting to disclose their pregnancy status to their health care providers, and providers have good reasons for considering in what circumstances the knowledge of a patient's undesired pregnancy may complicate care.

Table 2. Scripting for Opt-In Pregnancy Testing

Opt-In Consent Topic	Possible Scripting	Clinical, Legal, or Ethical Concept Highlighted
Introduce the need for testing	"Before we start today's visit, usually we test for pregnancy. This test is done to ensure safety for your care."	Benefits
Describe what the test can and cannot determine.	"Urine pregnancy tests would indicate if you may be pregnant as early as 10 days. A urine pregnancy test could also be positive up to 6 weeks after an abortion or a miscarriage."	Scope
Review what the urine will and will not be used for.	"With your consent, we will use your urine sample only for pregnancy testing. If, based on the rest of the visit other testing is recommended, such as for an infection, we will revisit this conversation to be sure you are aware of those tests."	Limitations to consent
Discuss the possible impact of the results.	"For today's care, we presume your test will be negative. If your test is positive, we would discuss the following about your care (such as all-options counseling and referral, referral-only for prenatal care)". "If your test is positive, we may need to modify the plan of care." "We will not be able to continue today's care for the following reasons…" "Guidelines in this health care practice or laws in this state might impact your decision-making for a positive pregnancy test in the following ways…"	Risks
Outline documentation of the results.	"Like all testing and counseling, the pregnancy test results will be documented in your health care record. This record can be accessed by…"	Health care record as legal document
Review alternatives.	"You can decline pregnancy testing today. Here is how the care would be modified if so… You can choose to complete a pregnancy test at home before coming in for your next visit so you can privately determine the results and decide next steps…"	Informed consent
Receive consent to or decision against pregnancy testing.	"I respect your decision. Please let me know if your decision changes or if you have any questions and want to return to this conversation. Here's how we will proceed today with care…"	Respect for patient autonomy

Toward Opt-In Consent for Pregnancy Testing

We consider pregnancy testing similar to urine toxicology testing. In that clinical context, multiple state laws denote the legal ramifications to the pregnant person if certain substances, such as opioids or cocaine, are detected; these range from investigation by agents of the family regulation system to terminating parental custody. Over the last decade, illicit substance use during pregnancy has been used to justify incarceration of pregnant people.[12] In 2001, the *Ferguson v. City of Charleston* ruling affirmed that drug testing without consent was unconstitutional. Although the intention of the testing was to get pregnant people into rehabilitation programs and monitor their sobriety during pregnancy, the court recognized the imminent threat to privacy, bodily integrity, and autonomy this practice caused, and the undue harms potentiated by the collaboration of the medical system with law enforcement.[13] These same tactics are now being used against people seeking abortion in criminalizing states. To preserve patient decisional autonomy regarding what information about their bodies they wish to know, we propose an opt-in approach to pregnancy testing.

Clinically speaking, an opt-in approach to pregnancy testing can take many forms. In nonemergency outpatient and inpatient settings, the care team would discuss with the patient the reason to order a pregnancy test, what the test may demonstrate in the context of the person's clinical presentation, and how it might aid in either making a diagnosis or further management. Situating the discussion within the legal environment and considering any relevant implications for the patient and provider related to counseling, referral, and clinical documentation would fully actualize the "risks" discussion of the informed counseling process. Table 1 lists specific recommendations for various clinical settings. Table 2 offers possible language that providers and clinical staff might consider depending on setting and need.

If or When Someone Declines

Declining laboratory testing is always within the patient's prerogative, regardless of pregnancy status, for any reason.[14] Failing to diagnose a pregnancy poses 2 types of potential risks: risk of injury to the potentially pregnant patient, and risk of injury to a potential embryo or fetus. There may be risks of bleeding or miscarriage from a colposcopy or endometrial biopsy in the setting of an undiagnosed pregnancy, or teratogenicity caused by ionizing radiation from imaging procedures. However, radiology and obstetric professional organizations' practice parameters support a patient's right to decline pregnancy testing and to still proceed with procedures or imaging.[15–16] In such scenarios, shared decision-making encourages an informed dissent process identical to the informed consent process, including harm reduction options as part of the full discussion of risks, benefits, and alternatives.[17] Documenting this discussion and the patient's decision, as with any consent to or decision against recommended care, is important and can minimize provider liability for failure to diagnose a pregnancy.

Centering the person forgoing a requested diagnostic test values patient autonomy and nonmaleficence as paramount. Respecting bodily and decisional autonomy implicates nonmaleficence since disregarding a patient's decision to decline pregnancy testing would, at a minimum, risk inflicting psychological harm and could, at a maximum, activate a legal chain risking their physical safety. Irreversibility or seriousness of potential harm does not justify acting contrary to a patient's choice when that choice occurs within the clinical ethical informed consent process. Applying the cultural safety framework, which invites health professionals and institutions to "acknowledge and address their own biases, attitudes, assumptions, stereotypes, prejudices, structures and characteristics that may affect the quality of care provided,"[18(p14)] resolves conflicts arising between a clinical team strongly recommending a pregnancy test based on safety concerns and a patient who declines. What counts as culturally safe is defined by the individual to whom the services are being delivered, which requires respecting their informed dissent. Neglecting the cultural safety framework in this context heightens the risk of psychologically wounding the patient by insulting their autonomy.

DISCUSSION

Pregnancy test results have always had major ramifications for individuals' lives, particularly for patients multiply disenfranchised and oppressed by nature of their age, state, race, ethnicity, sex, gender, sexual orientation, insurance coverage, language, citizenship, disability, or other identities. Opt-out pregnancy testing risks harm by ignoring these complex and potentially harmful effects of diagnosing a pregnancy. The post-*Dobbs* legal environment further complicates this reality. Sexual and reproductive health care is best served by embracing the reproductive justice framework, wherein the patient's choice to become pregnant, decision to parent, and ability to parent in safe communities, are all impacted by the pregnancy test.

Our argument primarily addresses the ethical approach to consent to UPT, while recognizing legal implications for the diagnosis of pregnancy. We hope this discussion creates pause for providers conducting pregnancy testing in any setting, including in emergency situations, with incompetent patients, or those with limited decision-making capacity, as the ramifications would be similar. The pregnancy testing guidance and scripting offered in the corresponding tables can help determine if a test is necessary at all, and how to discuss testing decisions with patients, surrogate decision-makers, or the care team.

CONCLUSION

Opt-in consent to pregnancy testing is the most conscientious, ethical, and patient-centered approach. Recognizing social and legal consequences patients and providers may face when confronted with an undesired positive test result also acknowledges that opt-out pregnancy testing can lead to significant patient harm. Opt-in testing may present new challenges of reorganization to workflows and providers respecting the process of informed dissent, however opt-in UPT is the conscientious method that centers the patient's lived experience. The post-*Dobbs* legal landscape limits options for pregnancy-capable people; it is imperative that health care providers act on their duty to advocate for clients by protecting their rights. Recognizing pregnancy testing as a nonneutral health care decision, providers can consider how best to communicate the reasons for testing and possible implications in partnership with their patients and proceed based on self-determination and explicit consent.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

REFERENCES

1. *Dobbs v Jackson Women's Health Org*, 142 SCt 2228 (2022).
2. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 8th ed. Oxford University Press; 2019.
3. American College of Obstetricians and Gynecologists. Informed consent and shared decision making in obstetrics and gynecology. Committee Opinion No. 819. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2021;137:e34-e41.
4. *Roe v Wade*, 410 US 113 (1973).
5. Cohen DS, Donley G, Rebouché R. The new abortion battleground. *Colum L Rev*. 2023;52(1):1-100.
6. Ala Code §26-23H-4; §26-23H-6 (2022).
7. Ill Pub Act 102-1117 HB 4664, 102d Gen Assembly (2023).
8. US Const. art. IV, § 2.
9. Tx Health and Safety Code Ann § 171.208(a) (West, Westlaw through 2021 Legis Sess).
10. HIPAA privacy rule and disclosures of information relating to reproductive health care. US Department of Health and Human Services website. Published June 29, 2022. Accessed February 26, 2023. https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html#footnote9_2qo78ma
11. Federal Child Abuse Prevention and Treatment Act, 42 USC § 510a(b)(2)(B)(i) (2019).
12. Criminalizing pregnancy: policing pregnant women who use drugs in the USA. Amnesty International website. Published online May 23, 2017. Accessed February 28, 2023. https://www.amnesty.org/en/documents/amr51/6203/2017/en/
13. *Ferguson v. City of Charleston*, 532 US 67 (2001)
14. International Federation of Gynecology and Obstetrics. *FIGO Ethics and Professionalism Guidelines: Current Ethical Challenges in*

Obstetric and Gynecologic Practice, Research, and Education. Jaypee Brothers Medical Publishers Ltd; 2019.
15. American College of Obstetricians and Gynecologists. Committee opinion no. 723 summary: guidelines for diagnostic imaging during pregnancy and lactation. *Obstet Gynecol*. 2017;130(4):933–934.
16. American College of Radiology, Society for Pediatric Radiology. *ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women With Ionizing Radiation*. American College of Radiology; 2018.
17. Conti AA. From informed consent to informed dissent in health care: historical evolution in the twentieth century. *Acta Bio Medica Atenei Parmensis*. 2017;88(2). doi:10.23750/abm.v88i2.5441
18. Curtis E, Jones R, Tipene-Leach D, et al. Why cultural safety rather than cultural competency is required to achieve health equity: a literature review and recommended definition. *Int J Equity Health*. 2019;18(1):174. doi:10.1186/s12939-019-1082-3
19. How to be reasonably certain that a woman is not pregnant. Centers for Disease Control and Prevention website. Published 2016. Accessed February 28, 2023. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/notpregnant.html
20. Min J, Buckel C, Secura GM, Peipert JF, Madden T. Performance of a checklist to exclude pregnancy at the time of contraceptive initiation among women with a negative urine pregnancy test. *Contraception*. 2015;91(1):80-84.